IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for Reissue of: Patent No. 5,443,833		§	
Patentees:	ANDREW R. CLARK PAUL WRIGHT JULIA H. RATCLIFFE	§ § §	Attorney Docket No.: 2553.004
Assignee:	Fisons, plc	§	
Issued:	August 22, 1995	§	
For:	PHARMACEUTICAL COMPOSITIONS	§	

REISSUE DECLARATION OF ALISON BLAKEY UNDER 37 C.F.R. 1.175(b)

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

As one of the attorneys who prosecuted the applications which ultimately issued as U.S. Patent No. 5,443,833 on August 22, 1995, I hereby declare:

1. My residence, post office address and citizenship are as stated below, underneath my name.

2. I was employed by Fisons plc ("Fisons") from October 1990 to May 1995 as a trainee patent attorney.

3. From January, 1991 I was the primary in-house attorney involved in the

prosecution of U.S. Serial Application 08/082,804, a continuation of U.S. Serial Application 07/742,574, which was a continuation of U.S. Serial Application 07/410,020, which was a continuation of 07/133,520 (collectively referred to as "the application").

4. Upon receiving the final rejection of the claims pending in U.S. Serial Application No. 08/082,804 dated October 19, 1994, which included claims directed to the treatment of various conditions including ophthalmic conditions and reversible obstructive airways disease (ROAD), i.e. claim 18, I instructed the United States associate of Marshall, O'Toole, Gerstein, Murray & Borun to cancel those pending claims and add claims directed solely to a method of treatment of ROAD. In accordance with this instruction, the law firm of Marshall, O'Toole, Gerstein, Murray & Borun filed an Amendment after final rejection having a Patent and Trademark mailroom stamp dated February 16, 1995 which canceled the pending claims, including claim 18, and presented three new claims limited to a method of treating a ROAD.

5. In early 1995, the Research and Development function of Fisons was acquired by Astra Pharmaceuticals Limited (Astra). As a result of this acquisition, on May 24, 1995, all Fisons in-house patent attorneys transferred to Astra. As Fisons was left with no in-house patent attorneys, responsibility for this file and others was transferred in May, 1995 to the law firm of Lewis and Taylor in Great Britain. Later in 1995, Fisons was acquired by Rhône-Poulenc Rorer (RPR).

6. It was my usual practice, and that of Fisons, that when claims in a pending patent application were limited to one aspect of the invention and such claims were allowed, and other aspects of the previously submitted claims had been canceled, to ask the United States associate to file a continuing application before the subject matter issued as a patent. In this case, I did not

make such a request to the U.S. associate before I left the employment of Fisons in May 1995. Further, it appears that no one else acted on this omission and hence the United States associate was not instructed to file a continuing application. Thus, continuing prosecution of the ophthalmic invention was not progressed.

7. It appears that in the months immediately preceding issue of U.S. Patent No. 5,443,833, when the responsibility for prosecution of the application changed, a continuing application was not sought. In early 1995, two of the three inventors, Julia Ratcliffe and Andrew Clark were no longer in the employ of Fisons. The third inventor, Paul Wright, was engaged in other research projects with Fisons and on May 24, 1995 he too transferred to Astra. The inventors were not aware of the cancellation of the pending claims and submission of the new claims in the Amendment after the Final Rejection.

8. Even though the United States and Patent and Trademark Office examiner's Final Rejection did not cite prior art specifically directed to methods of treating various ophthalmic diseases and controlling the symptoms of various ophthalmic conditions, I requested that the pending claims be canceled and the new claims be added. The claims related to methods of treatment of ROAD were of primary importance to Fisons. At the time the response to the final rejection was filed, it was seen as particularly important to obtain claims related to methods of treatment of ROAD since Fisons was in the process of filing an NDA for nedocromil sodium nebulizer solution and a granted patent issuing from U.S. Serial Application No. 08/082,804 would benefit from a term of 17 years from grant.

9. I verily believe, as a result of the circumstances described above, the original patent is wholly or partly inoperative or invalid by reason of the patentees claiming less than they

had a right to claim in the patent. Specifically, the original patent is limited to the use of the aqueous pharmaceutical solution for treating ROAD and does not cover treating and controlling the symptoms of ophthalmic conditions, support for which can be found in the specification as originally filed.

10. This error arose entirely from inadvertence, accident and mistake and without any fraudulent and/or deceptive intent on my part, or, on my best information and belief, without any fraudulent and/or deceptive intent on the part of anyone associated with me.

I declare further that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

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Dated: August 21, 1997

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